DEC 1 0 2002

Summary Information

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K023875

1. **Submitter name, address, contact**

Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, New York 14626-5101
(585) 453-4041

Contact Person: Marlene A. Hanna

2. **Preparation date**

Date Special 510(k) prepared: November 20, 2002

3. **Device name**

Trade or Proprietary Name:
VITROS Chemistry Products ALB Slides
VITROS Chemistry Products Calibrator Kit 4
Common Name : Albumin test
Classification Name: Albumin test system (21 CFR 862.1035).

4. **Predicate device**

The VITROS Chemistry Products ALB Slides (modified) and VITROS Chemistry Products Calibrator Kit 4 are substantially equivalent to the VITROS Chemistry Products ALB Slides (current slide) and VITROS Chemistry Products Calibrator Kit 4.

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5. Device description

The VITROS Chemistry System uses *Vitros* Slides to perform discrete chemistry tests on body fluid specimens. All reactions necessary for a single quantitative measurement take place within the multi-layered analytical element of a *Vitros* Slide.

The system is comprised of two main elements:

1. The VITROS Chemistry Products range of chemistry products (in this case VITROS Chemistry Products ALB Slides, VITROS Chemistry Products Calibrator Kit 4, which are combined by the VITROS Chemistry System to perform the VITROS ALB test.

2. The VITROS Chemistry System – instrumentation, which provides automated use of the chemistry slides. Multiple VITROS Chemistry Systems were cleared for market by separate 510(k) pre-market notifications (K890928, K890929, K922072, K946090 and K922072).

The VITROS Chemistry System and Calibrators are dedicated specifically for use only with the VITROS Chemistry Products range of products.

6. Device intended use

VITROS ALB Slides
For in vitro diagnostic use only.
VITROS ALB Slides quantitatively measure albumin (ALB) concentration in serum and plasma.

VITROS Calibrator Kit 4
For in vitro diagnostic use only.
VITROS Calibrator Kit 4 is intended for use in calibration of the VITROS Chemistry Systems for the quantitative measurement of ALB, BuBc, Fe, TBIL, TIBC, and TP.

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7. Comparison to predicate device

The VITROS Chemistry Products ALB Slide (modified) and VITROS Chemistry Products Calibrator Kit 4 are substantially equivalent to VITROS Chemistry Products ALB Slide and VITROS Chemistry Products Calibrator Kit 4 which were cleared by the FDA for in vitro diagnostic use.
ALB Slide: (K812030, Cleared August 3, 1981)
Calibrator Kit 4: (K922072, July 19, 1992).

Table 1 lists the characteristics of the tests performed using the VITROS ALB Slide (modified) and the VITROS ALB Slide (current).

Table 1 List of Slide Characteristics: Comparison to Predicate Device

Device Characteristic	New Device VITROS ALB Slide (Modified)	Predicate Device VITROS ALB Slide (Current)
Sample volume	5.5 µL	10 µL
Quantity of Reactive Ingredients per slide (test)	Bromcresol green dye: 125.4 µg	Bromcresol green dye: 250 µg
Concentrations of Slide Reactive Ingredients per cm-squared	No Change.	Bromcresol green: 139.4 µg /cm^2
Intended Use	No change.	For in vitro diagnostic use only. VITROS ALB Slides quantitatively measure albumin concentration in serum and plasma.
Basic principle	No Change.	Dry, multilayered slide utilizing reflectance spectrophotometry
Sample type	No Change.	Serum , plasma
Reportable Range Serum, Plasma	No Change.	1.0 – 6.00 g/ dL (Conv. Units) 10.0 – 60.0 g/L (SI Units) 152 – 912 µmol/L (Alternate Units)
Instrumentation	No Change.	VITROS 250, 500, 750 and 950 Series Analyzers
Incubation time and temperature	No Change.	Approximately 5 minutes at 37°C

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8. Conclusions The information presented in the pre-market notification demonstrates that the performance of the VITROS ALB Slides (modified) for use with human serum and plasma is substantially equivalent to the cleared predicate device.

Equivalence was demonstrated using manufactured slides along with patient and quality control samples with measured albumin values spanning the assay range.

The information presented in the premarket notification provides a reasonable assurance that the VITROS ALB Slides (modified) for use with human serum and plasma is safe and effective for the stated intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 1 0 2002

Ms. Marlene A. Hanna
Regulatory Affairs Associate
Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, New York 14626-5101

Re: k023875
Trade/Device Name: VITROS Chemistry Products ALB Slides/
VITROS Chemistry Products Calibrator Kit 4
Regulation Number: 21 CFR § 862.1035
Regulation Name: Albumin test system
Regulatory Class: II
Product Code: CIX; JIX
Dated: November 20, 2002
Received: November 21, 2002

Dear Ms. Hanna:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Statement of Intended Use

510(k) Number (if known): K023875

Device Name:

VITROS Chemistry Products ALB Slides
VITROS Chemistry Products Calibrator Kit 4

Intended Use:

VITROS Chemistry Products ALB Slides
For in vitro diagnostic use only.
VITROS ALB Slides quantitatively measure albumin (ALB) concentration in serum and plasma.

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Summary and Explanation of Test:

Of all serum proteins, albumin is present in the highest concentration. It maintains the plasma oncotic pressure and the transport of many substances. Increased serum albumin may indicate dehydration or hyperinfusion with albumin; a decrease is found in rapid hydration, overhydration, severe malnutrition and malabsorbtion, severe diffuse liver necrosis, chronic active hepatitis, and neoplasia. Albumin is commonly reduced in chronic alcoholism, pregnancy, renal protein loss, thyroid dysfunction, peptic ulcer disease, and chronic inflammatory disease.[1]

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Carol C Benson for Jean Cooper

(Division Sign-Off)

Division of Clinical Laboratory Devices

510(k) Number K023875

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)